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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
08/479,995	06/07/1995		ROBERT G. PERGOLIZZI	ENZ-(D1)(C2)	8797
28171	7590	10/19/2005		EXAMINER	
ENZO BIO			MARSCHEL, ARDIN H		
527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022				ART UNIT	PAPER NUMBER
	•			1631	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)		
08/479,995	PERGOLIZZI ET AL.	PERGOLIZZI ET AL.	
Examiner	Art Unit		
Ardin Marschel	1631		

Advisory Action Before the Filing of an Appeal Brief -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 20 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires 4 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of 2. The Notice of Appeal was filed on filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDM**ENTS 3. 🔀 The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See attached explanation. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. Tor purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: See attached list. Claim(s) objected to: _____. Claim(s) rejected: See attached list. Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. 🛛 The request for reconsideration has been considered but does NOT place the application in condition for allowance because: for reasons of record as further explained as attached. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).

U.S. Patent and Trademark Office PTOL-303 (Rev. 7-05)

13. ☐ Other: .

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DETAILED ACTION

Further explanation of item # 3 on the enclosed Advisory action:

The proposed amendment, filed 9/20/05, included new claims 550-552 which contain NEW MATTER. Applicants' Remarks pointed to page 57, Example 31, for written support for said claims 550-552. Consideration of said page 57 Example reveals a number of limitations not in claims 550-552. Firstly, the Ig attachment is via end labeling whereas claims 550-552 lack such end antibody attachment and thus contains NEW MATTER due to being broader in scope, inclusive of antibody attachment anywhere on the claimed polynucleotide sequence. Secondly, the end labeling in Example 31 specifically requires derivatization of Fd DNA with 2,4,5-trichloroaniline, DCTA-SH, and periodate oxidation with cysteamine followed by sodium borohydride reduction; none of which are limitations of claims 550-552. Claims 550-552 therefore contain NEW MATTER due to their breadth being greater than said Example 31 disclosure. Additionally, claim 551 cites a monoclonal antibody which is not disclosed as filed, nor in said Example 31.

It is also noted that the proposed amendment cancels various NEW MATTER containing claims, such as claim 366, but fails to amend claims dependent therefrom, such as claim 367, thus adding the new issue of claim 367 depending from a canceled claim. Claims dependent from proposed claims to cancel, claims 370, 375, 379, 384, 388, 393, and 397 also raise this new issue as depending from said canceled claims.

Thus, the proposed amendment, filed 9/20/05, is denied entry due to raising new issues of NEW MATTER and confusing claim dependence which would require further consideration and/or search.

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Further explanation of item # 11 on the enclosed Advisory action:

The NEW MATTER rejection of claims 366-380, 384-398, 402, and 408 is maintained and reiterated from the previous office action, mailed 5/27/05. The cancellation of the NEW MATTER containing claims would have overcome this rejection if it had been entered.

Rejected claims are: 366-380, 384-398, 402, and 408

Allowed claims are: 283-362, 364, 365, 382, 383, 400, 401, 403, 404, 406, 407, 409-439, 441-505, 507, 508, 510, 511, and 528-547

Applicants are reminded of the availability of a second submission under 37 CFR 1.129(a).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 16, 2005

ARDIN H. MARSCHEL SUPERVISORY PATENT EXAMINER